

**CRITERIA FOR PRIOR AUTHORIZATION**

Keytruda® (pembrolizumab)

**PROVIDER GROUP** Professional**MANUAL GUIDELINES** The following drug requires prior authorization:  
Pembrolizumab (Keytruda®)**CRITERIA FOR PRIOR AUTHORIZATION APPROVAL** (must meet all of the following):

- Patient must have one of the following:
  - Diagnosis of unresectable or metastatic melanoma
    - Patients with BRAF V600 mutation positive tumor(s) should have disease progression (on approved V600 mutation directed therapy) prior to receiving pembrolizumab
  - Diagnosis of metastatic non-small cell lung cancer (NSCLC)
    - Have high PD-L1 expressing tumors (TPS  $\geq$  50%, as determined by a FDA approved test) without other genetic mutations and are treatment naive
    - Have PD-L1-expressing tumors (TPS  $\geq$  1% as determined by a FDA approved test) and have had disease progression on or after platinum-containing chemotherapy
    - Patients with EGFR or ALK genomic tumor aberrations should have disease progression (on approved EGFR- or ALK-directed therapy) prior to receiving pembrolizumab
  - Diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck
    - Have had disease progression on or after platinum-containing chemotherapy
- Must be prescribed by, or in consultation with, an oncologist or hematologist
- Patient must be 18 years of age or older
- Patient must not be pregnant or nursing
- Must be administered by a healthcare professional
- Dose does not exceed FDA approved maximum dosing limits
  - For melanoma, maximum dose is 2 milligrams per kilogram administered intravenously every 3 weeks
  - For non-small cell lung cancer or squamous cell carcinoma of the head and neck, maximum dose is 200 mg administered intravenously every 3 weeks for a maximum duration of 24 months

**LENGTH OF APPROVAL:** 12 months**Notes:**

- Information on FDA-approved tests for the detection of PD-L1 expression in NSCLC is available at:  
<http://www.fda.gov/CompanionDiagnostics>.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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PHARMACY PROGRAM MANAGER  
DIVISION OF HEALTH CARE FINANCE  
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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